CDER GUIDANCES

NEW/REVISED/WITHDRAWN

1/1/2004 –12/14/2004

(Sorted by date)

Title	Subject	Level at Date of Issue	Publication/ Withdrawal Date	Status
Drug Substance: Chemistry, Manufacturing, and Controls Information	Chemistry Draft	Level 1	1/7/2004	New
IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer	Clinical Medical	Level 2	1/15/2004	Revised
Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions	Procedural Draft	Level 1	1/27/2004	New
E2C Addendum – Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs	ICH – Efficacy	Level 1	2/5/2004	New
Providing Regulatory Submissions in Electronic Format – Content of Labeling	Electronic Submissions Draft	Level 1	2/5/2004	New
"Help-Seeking" and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms	Advertising Draft	Level 1	2/10/2004	New
Time and Extent Applications	OTC Draft	Level 1	2/10/2004	New
Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements	Advertising Draft	Level 1	2/10/2004	New
Labeling for Noncontraceptive Estrogen Drug Products for the Treatment of Vasomotor Symtoms and Vulvar and Vaginal Atrophy Symptoms – Prescribing Information for Health Care Providers and Patient Labeling	Labeling Draft	Level 1	2/17/2004	New
Labeling for Combined Oral Contraceptives	Labeling Draft	Level 1	3/5/2004	New

Potassium Iodide Tablets Shelf Life Extension for Federal Agencies and State and Local Governments	Procedural	Level 1	3/8/2004	New
Vaccinia Virus – Developing Drugs to Mitigate Complications From Smallpox Vaccination	Clinical Antimicrobial Draft	Level 1	3/9/2004	New
Q5E – Comparability of Biotechnology/Biological Products Subject to Changes in Their Manufacturing Process	ICH Draft – Quality	Level 2	3/30/2004	New
E2E – Pharmacovigilance Planning (PvP)	ICH Draft – Efficacy	Level 2	3/30/2004	New
Changes to an Approved NDA or ANDA	Chemistry	Level 1	4/8/2004	Revised
Exocrine Pancreatic Insufficiency Drug Products-Submitting New Drug Applications	Clinical Medical Draft	Level 1	4/28/2004	New
Combination Products Timeliness of Premarket Reviews	Clinical Medical Draft	Level 1	5/4/2004	New
Premarketing Risk Assessment	Clinical Medical Draft	Level 1	5/5/2004	New
Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment	Clinical Medical Draft	Level 1	5/5/2004	New
Development and Use of Risk Minimization Action Plans	Clinical Medical Draft	Level 1	5/5/2004	New
E2B(M): Data Elements for Transmission of Individual Case Safety Reports, Questions and Answers	ICH – Efficacy	Level 2	5/5/2004	Revised
M4: The CTD – Efficacy Questions and Answers	ICH – Efficacy	Level 2	5/5/2004	Revised
M4: The CTD – General Questions and Answers	ICH – General	Level 2	5/5/2004	Revised
Fixed Dose Combination and Co-Packaged Drug Products for Treatment of HIV	Procedural Draft	Level 1	5/19/2004	New

Handling and Retention of Bioavailability and Bioequivalence Testing Samples	Generic Drug	Level 1	5/26/2004	New
E5 – Ethnic Factors in the Acceptability of Foreign Clinical Data, Questions and Answers	ICH – Efficacy	Level 2	6/4/2004	New
Q1E – Evaluation of Stability Data	ICH – Quality	Level 1	6/8/2004	New
M4 – The CTD – Quality Questions and Answers/Location Issues	ICH – Joint Safety/Efficacy (Multidisciplinary)	Level 1	6/9/2004	New
Botanical Drug Products	Chemistry	Level 1	6/9/2004	New
Developing Medical Imaging Drug and Biological Products; Part 1: Conducting Safety Assessments	Clinical Medical	Level 1	6/22/2004	New
Developing Medical Imaging Drug and Biological Products; Part 2: Clinical Indications	Clinical Medical	Level 1	6/22/2004	New
Developing Medical Imaging Drug and Biological Products; Part 3: Design, Analysis, and Interpretation of Clinical Studies	Clinical Medical	Level 1	6/22/2004	New
Q1F – Stability Data Package for Registration in Climatic Zones III and IV	ICH – Quality	Level 2	7/1/2004	Revised
FDA Export Certificate	Procedural	Level 2	7/12/2004	New
Clinical Evaluation of Antacid Drugs	Clinical Medical	Level 1	7/20/2004	Withdrawn
Clinical Evaluation of Antidiarrheal Drugs	Clinical Medical	Level 1	7/20/2004	Withdrawn
Clinical Evaluation of Gastric Secretory Depressant (GSD) Drugs	Clinical Medical	Level 1	7/20/2004	Withdrawn
Clinical Evaluation of Laxative Drugs	Clinical Medical	Level 1	7/20/2004	Withdrawn

Clinical Evaluation of Radiopharmaceutical Drugs	Clinical Medical	Level 1	7/20/2004	Withdrawn
FDA Requirements for Approval for Drugs to Treat Superficial Bladder Cancer	Clinical Medical	Level 1	7/20/2004	Withdrawn
Available Therapy	Clinical Medical	Level 1	7/23/2004	New
Calcium DTPA and Zinc DTPA Drug Products – Submitting a New Drug Application	Clinical Medical	Level 2	8/13/2004	Revised
The Use of Clinical Holds Following Clinical Investigator Misconduct	Clinical Medical	Level 1	9/2/2004	Revised
E14 Clinical Evaluation of QT/OTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs	ICH	Level 1	9/13/2004	New
S7B Safety Pharmacology Studies for Assessing the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals	ICH	Level 1	9/13/2004	New
Application User Fees for Combination Products	Combination Products (Drug/Device/Biologic)	Level 1	9/28/2004	New
Computerized Systems Used in Clinical Trials	Clinical Medical	Level 1	10/4/2004	New
Current Good Manufacturing Practices for Combination Products	Combination Products (Drug/Device/Biologic)	Level 1	10/4/2004	New
Process Analytical Technology – A Framework for Innovative Pharmaceutical Manufacturing and Quality Assurance	Current Good Manufacturing Practices	Level 1	10/4/2004	New
Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations	Current Good Manufacturing Practices	Level 1	10/4/2004	New
Sterile Drug Products Produced by Aseptic Processing	Current Good Manufacturing Practices	Level 1	10/4/2004	New
Pharmakinetics in Pregnancy – Study Design, Data Analysis, and Impact on Dosing and Labeling	Clinical Pharmacology	Level 1	11/1/2004	New

Listed Drugs, 30 Month Stays, and Approval of Abbreviated New Drug Applications and 505(b)(2) Applications under Hatch-Waxman as Amended by the Medicare Prescription Drug, Improvement and Modernization Act of 2003; Q and A	Generics	Level 1	11/4/2004	New
Changes to an Approved New Drug Application or Abbreviated New Drug Application; Specifications – Use of Enforcement Discretion for Compendial Changes	Chemistry	Level 1	11/22/2004	New
Role of HIV Drug Resistance Testing in Antiretroviral Drug Development	Clinical Antimicrobial	Level 1	11/29/2004	New
In-Vivo Bioequivalence Studies Based on Population and Individual Bioequivalence Studies	Generics	Level 1	12/2/2004	Withdrawn